

**PUBLIC HEALTH DEPARTMENT[641]**

**Adopted and Filed**

Pursuant to the authority of Iowa Code section 135.11, the Department of Public Health hereby amends Chapter 10, “Iowa Get Screened Colorectal Cancer Program,” Iowa Administrative Code.

These amendments remove references to the Centers for Disease Control and Prevention (CDC), its screening guidelines, and data requirements. This change is the result of a change in funding priority made by the CDC for the five-year period beginning June 30, 2015. This funding change also removed the requirement of the Medical Advisory Board (MAB), and these amendments remove reference to the MAB and its associated definitions. The amendments change the program’s screening eligibility requirements for income levels up to 300 percent of the federal poverty level (FPL) from 250 percent of the FPL and for the screening age from 64 years of age to 75 years of age to encourage access to services. The amendments remove references to IowaCare and replace them with references to the health insurance marketplace and Medicaid. The amendments allow for contractor calls instead of site visits for the provision of technical assistance and evaluations. The amendments also remove requirements to reflect current programming, such as professional development, in-reach at Federally Qualified Health Centers, and coalition development.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 2446C** on March 16, 2016. A public hearing was held on April 5, 2016.

Two comments were received from the American Cancer Society’s Cancer Action Network. The first comment related to language regarding in-reach that was struck from renumbered subrule 10.3(6). The commenter noted that it is important for the Iowa Get Screened Program to continue to have an in-reach process in place. No changes were made to the amendments based on this comment. In-reach is a method that will continue to be used for recruitment of participants. The language in the referenced subrule pertains only to in-reach targeted at Federally Qualified Health Centers. The second comment supported raising the eligibility requirements of the program to help ensure access to services.

These amendments are identical to those published under Notice of Intended Action.

The Department adopted these amendments on May 11, 2016.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 135.11 and 2015 Iowa Acts, Senate File 505, section 3(3h).

These amendments will become effective July 13, 2016.

The following amendments are adopted.

ITEM 1. Amend rule 641—10.1(135) as follows:

**641—10.1(135) Purpose.** ~~The Iowa get screened (IGS): colorectal cancer program was established in 2009 through a cooperative agreement with the Centers for Disease Control and Prevention and is administered by the department. The goal of the IGS program is to reduce the incidence, mortality and prevalence of colorectal cancer in Iowa by increasing the number of men and women who receive colorectal cancer screenings. Through the program, fecal immunochemical tests (FITs) and colonoscopies will be are provided to eligible Iowans. Along with providing screenings, the program also facilitates supportive services and referral for diagnosis and treatment to Iowans with abnormal screening results. Iowans who are eligible to enter the program must be 50 to 64 75 years of age, be underinsured or uninsured, have incomes of up to 250 300 percent of the federal poverty level (FPL) and have an average or increased risk for developing colorectal cancer.~~

ITEM 2. Amend the following definitions in rule **641—10.2(135)**:

~~“Colorectal cancer data elements” or “CCDE” means a set of standardized data elements developed by the Centers for Disease Control and Prevention, Division of Cancer Prevention and Control, used to~~

ensure that consistent and complete information is collected on participants whose screening or diagnosis was paid for through the IGS program with federal state funding.

*“Eligibility criteria”* means a set of questions that a potential participant is asked to ensure the participant meets program qualifying standards including targeted age, income guidelines, level of risk for colorectal cancer and screening determination guidelines. Qualifying standards ~~are outlined in the CDC’s Colorectal Control Cancer Program Policies and Procedures~~ and are based on recommendations from the United States Preventive Services Task Force (USPSTF).

*“In-reach”* means the method that will be used in the local program to recruit participants. In-reach targets existing clients through the Iowa care for yourself program ~~and federally qualified health centers.~~

*“Iowa get screened: colorectal cancer program”* or *“IGS program”* means the state program which provides limited screening services to eligible Iowans and funded through the federal Colorectal Cancer Control Program (CRCCP). ~~This program requires policy and systems change, public education and awareness and limited screening activities. The IGS program has been made possible in Iowa through a cooperative agreement awarded to the department through the competitive bid grants procurement process by the United States Department of Health and Human Services, Division of the Centers for Disease Control and Prevention.~~

*“Polyp”* means a growth from a mucous membrane commonly found in organs such as the colon and rectum, the uterus and the nose. Certain types of polyps, such as adenomas, may develop into cancer.

*“Underinsured”* means an individual with income at ~~250~~ 300 percent of the federal poverty guideline or lower with health insurance that has unreasonably high copayments, deductibles or coinsurance.

ITEM 3. Rescind the definitions of “Federally qualified health center,” “Medical advisory board” and “Radiologist” in rule ~~641—10.2(135).~~

ITEM 4. Amend subparagraph ~~10.3(2)“a”(2)~~ as follows:

(2) Colonoscopy every 10 years from initial screen or as prescribed by a physician ~~for surveillance~~ in accordance with USPSTF recommendations;

ITEM 5. Amend subparagraph ~~10.3(2)“b”(4)~~ as follows:

(4) Surgery or surgical staging, ~~unless specifically required and approved by the IGS program’s MAB to provide a histological diagnosis of cancer;~~

ITEM 6. Amend subparagraph ~~10.3(2)“b”(11)~~ as follows:

(11) Use of propofol as anesthesia during endoscopy, unless specifically required and approved by the IGS ~~program’s MAB~~ program in cases where the participant cannot be sedated with standard moderate sedation; and

ITEM 7. Amend paragraphs ~~10.3(5)“e”~~ to ~~“i”~~ as follows:

*e.* Accurate data collection and documentation.

~~(1) Colorectal cancer data elements (CCDEs) are reported to CDC semiannually by the department.~~

~~(2) Site visits Contractor calls are conducted at local program sites with staff to provide technical assistance, give feedback on program performance, evaluate case management process and if needed conduct a walk-through of current services to provide feedback.~~

*f.* Evaluation Program evaluation. ~~Workplans shall be reviewed and surveys conducted in the community and with program partners. Reports on progress and face-to-face meetings shall be conducted routinely and on an as-needed basis to assess how the IGS program is meeting CDC program objectives.~~

~~*g.* Process improvement and systems change activities.~~

~~*h.* Adherence to CDC policies and guidelines.~~

~~*i.* Approval and utilization of additions to the local program allowable procedures list.~~

ITEM 8. Amend subrules 10.3(6) to 10.3(10) as follows:

~~**10.3(6)** Professional development shall be provided by the IGS program and contracted local program staff through a variety of channels including educational activities that enable professionals to perform their jobs competently, to identify needs and resources, and to ensure that health care delivery systems provide appropriate clinical outcomes for colorectal cancer screening services.~~

~~10.3(7)~~ **10.3(6)** The IGS program and contracted local program staff shall provide in-reach education and recruitment that involve the systematic design and delivery of clear and consistent messages about colorectal cancer (CRC) and the benefits of early detection using a variety of methods and strategies. In-reach activities shall focus on men and women who have never or rarely been screened for CRC and shall work toward the removal of barriers to care screening (e.g., ~~by providing respite care, interpreter services and~~ transportation) through collaborative activities with other community organizations. ~~In-reach shall be targeted toward the participants already being served through the IA-CFY program and patients at FQHCs. Public education and outreach activities for community awareness of CRC are supported and mandatory for the project.~~

~~10.3(8)~~ The IGS program may develop coalitions and partnerships to establish a common agreement for sharing resources and responsibilities to achieve the common goal of reducing colorectal cancer mortality.

~~10.3(9)~~ **10.3(7)** The IGS program shall conduct surveillance utilizing continuous, proactive, timely and systematic collection, analysis, interpretation and dissemination of colorectal cancer screening prevalence, survival and mortality rates. Studies shall be conducted utilizing minimum data elements and other data sources to establish trends of disease, diagnosis, treatment, and research needs. IGS program planning, implementation and evaluation shall be based on the data.

~~10.3(10)~~ **10.3(8)** Evaluation ~~by the IGS program evaluator~~ shall be conducted through documentation of services, operation processes at the state and local program levels and outcomes of the IGS program. ~~The evaluation shall include face-to-face interviews with state and local IGS program staff involved in IGS program delivery. IGS program evaluation shall include suggestions to help IGS and local program staff meet the recommendations as set in the CRCCP program manual. Recommendations shall then be incorporated into the program workplan by the state staff.~~

ITEM 9. Rescind and reserve rule **641—10.4(135)**.

ITEM 10. Amend rule 641—10.5(135) as follows:

**641—10.5(135) Participant eligibility criteria.** An applicant for the IGS program must satisfy the criteria outlined in this rule. If an applicant does not meet these criteria, the applicant shall be provided information by contracted local program staff regarding ~~IowaCare, free care~~ the health insurance marketplace, Medicaid or sliding-fee clinics available in the area in which the applicant lives.

**10.5(1) Age.** Individuals 50 through 64 ~~75~~ years of age shall be the target population to receive colorectal cancer screening.

**10.5(2) Income.**

a. The IGS program income guidelines are based upon ~~250~~ 300 percent of the federal poverty level (FPL), which is set annually by the Centers for Medicare and Medicaid Services (CMS). New IGS program income guidelines will be adjusted following any change in CMS guidelines.

b. Self-declaration of income may be accepted.

c. Eligibility shall be based on net income for the household.

d. Assets shall not affect income status and shall not be counted when eligibility under the IGS program is determined.

**10.5(3) Insurance.**

a. The IGS program shall determine individuals to be uninsured if they do not have health insurance coverage.

b. The IGS program shall determine individuals to be underinsured if they have health insurance with unreasonably high copayments, deductibles or coinsurance or the insurance does not cover the IGS program's covered services.

c. Individuals who have Medicaid or Medicare Part B are not eligible. ~~Individuals who have IowaCare, Medicaid with spend-down, or Iowa family planning network may be eligible.~~

**10.5(4) Residency.**

a. Individuals must reside in the state of Iowa.

b. Individuals shall have an established address and contact information as needed for program staff to provide screening results, rescreens, and follow-up services.

**10.5(5) Risk level.** Individuals with an average or increased risk for developing colorectal cancer as defined by the recommendations of the USPSTF may qualify for IGS program services.

**10.5(6) Ineligible.** The IGS program does not provide coverage for:

- a. Individuals with Medicare Part B coverage.
- b. Individuals 49 years of age and younger.
- c. Individuals ~~65~~ 76 years of age and older.
- d. Individuals who do not have a primary care provider.
- e. Individuals at high risk for developing colorectal cancer. Individuals at high risk include:
  - (1) A genetic diagnosis of familial adenomatous polyposis (FAP) or hereditary nonpolyposis colorectal cancer (HNPCC),
  - (2) A clinical diagnosis or suspicion of FAP or HNPCC, or
  - (3) A history of inflammatory bowel disease (ulcerative colitis or Crohn's disease).
- f. Individuals experiencing the following gastrointestinal symptoms:
  - (1) Rectal bleeding, bloody diarrhea, or very dark blood in the stool within the past six months;
  - (2) Prolonged change in bowel habits;
  - (3) Persistent/ongoing abdominal pain;
  - (4) Recurring symptoms of bowel obstruction; or
  - (5) Significant unintentional weight loss.

ITEM 11. Amend subrule 10.7(1) as follows:

**10.7(1)** In the event the IGS program director certifies that there are inadequate funds to meet participants' needs, either attributable to a reduction in federal funding ~~from the CDC~~ or to a projected enrollment of participants in excess of anticipated enrollment, the program director may restrict new applicants' participation in the IGS program. First priority shall be given to individuals who have never been screened for CRC.

ITEM 12. Amend rule 641—10.9(135) as follows:

**641—10.9(135) Colorectal cancer treatment.** The IGS program does not pay for colorectal cancer treatment services. ~~A participant will be assisted with enrolling in the IowaCare program, in the event treatment services are needed.~~ If a participant needs treatment, the local program coordinator will refer the participant to an American Cancer Society patient navigator to identify and coordinate resources for the participant who may require physical, emotional, financial or other support through the cancer journey. The patient navigator and IGS program staff will work together to assist a participant needing treatment. It is an expectation of the cooperative agreement that a participant gets help obtaining treatment services free or at an affordable cost based on the participant's annual income and ability to pay for the services.

ITEM 13. Amend **641—Chapter 10**, implementation sentence, as follows:

These rules are intended to implement Iowa Code ~~sections~~ section 135.11(1) and ~~135.39 and 42 U.S.C. Section 241(a)~~, as amended 2015 Iowa Acts, Senate File 505, section 3(3h).

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/8/16.